In re Application of:
Jay Leng
Application No.: 09/619,047

Filed; July 19, 2000

Page 3

PATENT Attorney Docket No.: CHEM1110

## REMARKS

## Regarding the Amendments

Claims 3 and 5 to 8 have been amended as set forth in the above complete listing of the claims. These claims have been amended to incorporate the limitations of claim 1. By the present amendment, cancellation of claim 1 is requested, without prejudice.

As amended, the claims are supported by the specification and the original claims and do not add new matter. The amendments do not require a new search or raise new issues for consideration because they merely address issues already raised by the Examiner or define Applicants' invention more clearly. It is submitted that the amendments place the claims in condition for allowance or in better condition for appeal by reducing the number of issues for consideration on appeal. The amendments were not made earlier in the prosecution because it is maintained that the previously pending claims were allowable. Since the amendments do not add new matter or require a new search or consideration, and place the claims in condition for allowance or in better condition for appeal, entry of the amendment is respectfully requested.

#### Allowable Subject Matter

It is stated in the Advisory Action that claims 3 and 5 to 8 are rejected for being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. As discussed above, claims 3 and 5 to 8 have been amended accordingly. Therefore, allowance of claims 3 and 5 to 8 is respectfully requested.

## Rejection Under 35 U.S.C. § 112

Applicants respectfully traverse the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, for containing subject matter allegedly not described in the specification in such a way

Grey Cary\GT\6393091.1 105175-159907 In re Application of:
Jay Leng
Application No.: 09/619,047

Filed: July 19, 2000

Page 4

PATENT
Attorney Docket No.: CHEM1110

as to reasonably convey to one skilled in the relevant art that the inventors had possession of the invention at the time of filing of the Application. Applicants respectfully disagree.

Initially, the Examiner's attention is drawn to the Complete Listing of the Claims, as set forth above. It is noted that claim 1 has been canceled by the present amendment.

In particular, it is alleged in the Office Action mailed October 2, 2003 that claim 1 is directed to a modified Renilla luciferase having any recognition sites cleavable by any protease. Applicants respectfully disagree. The claims of the invention are not directed to just any modified Renilla luciferase having any recognition sites cleavable by any protease, but are particular to a polypeptide with a recognition site at residues 197-200 of SEQ ID NO: 2. The specification sets forth examples, meant to be illustrative and not limiting, which identify a recognition site located at residues 197-200 of SEQ ID NO: 2, where residue 198 is E and residue 200 is D. Such examples are as set forth in new claims 67-70, such as DEVD, VEHD, LETD, LEHD, IEPD, DETD, WEHD, YVAD and VEID. In addition to these structural requirements, the polypeptide of the invention must also have decreased luciferase activity upon cleavage by a protease.

Therefore, the claims of the invention meet the written description requirement of 35 U.S.C. §112, first paragraph. As rejected claim 1 has been canceled, it is respectfully submitted that the rejection is moot. Accordingly, removal of the rejection is requested.

Applicants respectfully traverse the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, for allegedly being non-enabled for luciferases substituted with an unknown recognition site at residues 197-200. Applicants respectfully draw the Examiner's attention to the cancellation of claim 1. As rejected claim 1 has been canceled, it is respectfully submitted that the rejection is moot. Accordingly, removal of the rejection is requested.

NO.519 P.8/8

APR. 1.2004 11:12AM GRAY CARY GT

In re Application of:
Jay Leng

Application No.: 09/619,047

Filed: July 19, 2000

Page 5

PATENT

Attorney Docket No.: CHEM1110

# CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 3 and 5 to 8 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 677-1456. Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: April 1, 2004

Lisa A. Haile, J.D., Ph.D. Registration No. 38,347 Telephone: (858) 677-1456 Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP 4365 Executive Drive, Suite 1100 San Diego, California 92121-2133 USPTO Customer Number 28213